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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/758,902 | 01/11/2001 | Roberts S. David | PC9047D | 1327 |

23913 7590 05/03/2007

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| EXAMINER | |
|---|---|
| DUFFY, PATRICIA ANN | |
| **ART UNIT** | **PAPER NUMBER** |
| 1645 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 05/03/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/758,902 | DAVID ET AL. | |
| | Examiner | Art Unit | |
| | Patricia A. Duffy | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *01 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *19 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10-16-06 (claim amendments) and 2-1-07 have been entered.

Claims 19 and 20 are pending and under examination.

### *Rejections Withdrawn*

The obvious double patenting rejection over US Patent 6,083,512 is withdrawn in view of the properly filed terminal disclaimer of 2-1-07.

The rejection of claim 20 under 35 U.S.C. 103(a) as being unpatentable over Seifert (Deutsche Tiearzliche Wochem. 90(7):274-279, 1983) in view of Geresi et al (Ann. Immunol. Hung. 25(0):37-40, 1985), Farmers and Consumers Market Bulletin (Department of Agriculture, Atlanta, Georgia, 70(24): 1984, page 1, 12, ill.), and Kensil (US Patent 5,057,540 issued 1991) is withdrawn in view of the new grounds of rejection set forth below and in view of the fact that the art did not teach a Clostridial vaccine composition wherein the composition of clostridial immunogens did not have endogenous adjuvants present.

The rejection of claim 19 under 35 U.S.C. 103(a) as being unpatentable over Seifert (Deutsche Tiearzliche Wochem. 90(7):274-279, 1983), Geresi et al (Ann. Immunol. Hung. 25(0):37-40, 1985), Farmers and Consumers Market Bulletin (Department of Agriculture,

Atlanta, Georgia, 70(24): 1984, page 1, 12, ill.), and Kensil (US Patent 5,057,540 issued 1991) as applied to claims 18 and 20 above further in view of Green et al (The Veterinary Record, 120:435-439, 1987) is withdrawn in view of the new grounds of rejection set forth below and in view of the fact that the art did not teach a Clostridial vaccine composition wherein the composition of clostridial immunogens did not have endogenous adjuvants present.

## *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims now recite that "saponin" is the sole adjuvant in the multicomponent clostridial vaccine composition of claims 19 and 20. It is noted that an immunogen can also function as an adjuvant and that the terms are not mutually exclusive. The vaccine composition may comprise immunogens from at least two or six or more species or serotypes of Clostridium and an antigen from a respiratory virus. It is noted that the immunogens described in the specification comprise toxins of different clostridial species including but not limtited to *Clostridium tetani* and *Clostridium difficile*.. The claims

encompass purified toxins or clarified cultures comprising the toxin(s) and whole cells comprising the toxins because the immunogens are not purified and a whole cells bacterin comprises "immunogens". Bacterial toxins were well known adjuvants at the time of this invention. See for example US Patent No. 5,695,766 teach toxin-based adjuvants such as tetanus toxin and similarly, US Patent No. 5,646,247, US Patent No. 5,583,112, US Patent 5,270,202 and Smith et al Journal of Dental Research V76, p 2668, 1997. The toxins/toxoids are both immunogens and adjuvants. Further, peptidoglycan and lipoteichoic acids are components of the cell wall of gram positive bacteria such as *Clostridia* spp (Dziarski et al , Cell. Mol. Life Sci, 60:1793-1804, 2003) and are also adjuvants causing activation of macrophages and secretion of mediators (see Dxiarski et al , page 1795, Table 1). Therefore, since the claims also read on whole cell bacterin vaccines comprising both toxins and cell wall components of Clostridia, the skilled artisan would immediately recognize that Applicants were not in possession of the now claimed invention. The contemplated and encompassed vaccines comprising immunogens as whole cell vaccines would necessarily comprise these immunogens that are also adjuvants. Further, the whole cell vaccines would necessarily comprise nucleic acid sequences comprising CpG repeats in the nucleic acid component that is also a known adjuvant (Heeg et al , Eur. J. Clin. Micrbiol. Infect. Dis. 17:464-469, 1998).

The specification as originally filed does not teach a multicomponent clostridial vaccine composition that comprises at least two or more Clostridial immunogens from different species in combination with a respiratory viral antigen and saponins wherein saponins is the sole adjuvant in the vaccine composition and one skilled in the art would recognize that Applicants had not described such and were not in possession of such a vaccine composition at the time that the invention was made.

***Status of the Claims***

Claims 19 and 20 stand rejected.

***Conclusion***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Examiner Jeffrey Siew can be reached on 571-272-0787.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patricia A. Duffy, Ph.D.
Primary Examiner
Art Unit 1645